

*COMPARATIVE STUDY BETWEEN STOOL
ANTIGEN TEST AND UPPER ENDOSCOPIC
FINDINGS IN DIAGNOSIS OF H. PYLORI IN
EGYPTIAN CHILDREN*

By

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ABSTRACT

Background: *Helicobacter Pylori (H.pylori) is one of the most important causes of dyspepsia and diagnosis can be made by invasive or non-invasive methods. Although endoscopy is recommended for the initial diagnosis of H. pylori infection, several non-invasive diagnostic tests such as the H. pylori stool antigen test (HpSA) are available and well validated even in children.*

Aim and objectives: *was to compare the accuracy of the noninvasive H. pylori Stool Antigen Test (SAT) applied on the stool samples with the invasive gold standard upper GIT endoscope and biopsy of patients with upper gastrointestinal complaints.*

Subjects and methods: *This was prospective, observational and analytic study that was carried out on fifty children presented by upper gastrointestinal (GIT) symptoms including recurrent abdominal pain, hematemesis, dyspeptic epigastric pain, vomiting at pediatric gastroenterology endoscopy unit at Al-Husseini university hospital, during the period from February 2021 till June 2021*

Result: *we found that, Age ranged from 2-17 years with mean value 9.38 ± 4.412 years. More than half of studied sample were male (64.0%). Also, our results showed that 17(34.0%) had Recurrent abdominal pain, 11(22.0%) had Hematemesis, 12(24.0%) had Dyspepsia, 20(40.0%) had Epigastric pain and 20(40.0%) had Vomiting. Stool H.pylori antigen of the studied group, H.pylori antigen were detected in 42 patients (84.0%). While using Upper GIT endoscope and biopsy finding it was found that H.pylori antigen were detected in 40 patients (80.0%).*

Conclusion: *our results revealed that the H.pylori was more prevalent in males with ages <10 years and the most prevalent symptoms are recurrent abdominal pain, hematemesis, dyspepsia, epigastric pain and vomiting. Both stool antigen test and upper git endoscope & biopsy finding give comparable results. There was highly significant correlation between both tests. As a non-invasive technique the stool*

antigen test is more preferred than other invasive techniques as upper G.I.T endoscope & biopsy.

Keywords: *Helicobacter pylori; Diagnosis, Endoscopy; Stool antigen test; Child*

INTRODUCTION

Helicobacter pylori (*H.pylori*) is classified as a gram-negative, spiral-shaped bacterium and a microaerophilic, fastidious, human pathogen. *H. pylori* infection is usually acquired in early childhood and it can persist throughout life without antibiotic treatment (**Bonifácio et al., 2014**).

Helicobacter pylori (*H pylori*) Infection is common, even in pediatric patients. In European children, serum positivity of immunoglobulin G (IgG) antibodies is almost 5% to 15%. The infection is likely acquired early in childhood; in developing countries, the incidence of the infection in infancy may be up to 50% (**Wang, et al., 2015**).

Helicobacter pylori is now recognized as related to gastritis and peptic ulcer disease. Furthermore, *H pylori* infection is involved in the pathogenesis of gastric adenocarcinoma and lymphoma in adulthood (**Zeng, et al., 2015**).

Invasive and non-invasive tests are used in the diagnosis of *H. pylori* infection. The invasive methods include culture, histology, and urease tests. Biopsy

specimens obtained with upper gastrointestinal endoscopy are necessary for these tests, the noninvasive methods include stool antigen test (SAT), urea breath test and serology (**Di Rienzo et al., 2013**).

Stool antigen tests are non-invasive and inexpensive methods to detect active *H. pylori* infection, Eradication of *H. pylori* infection is evaluated by SATs. Therefore this test is useful before and after *H. pylori* therapy (**Chey et al., 2007**).

The gold-standard diagnostic test remains endoscopy with biopsy analyses (histologic analysis and urease rapid test or culture of gastric biopsy specimens) (**Lopes, et al., 2014**).

This study aimed to compare the accuracy of the noninvasive *H. pylori* Stool Antigen Test (SAT) applied on the stool samples with the invasive gold standard upper GIT endoscope and biopsy of patients with upper gastrointestinal complaints.

Ethical Consideration:

1. A written informed consent was obtained from parents or the legal guardians before the study.
2. An approval by the local ethical committee was obtained before the study.
3. The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.
4. All the data of the patients and results of the study are confidential & the patients have the right to keep it.
5. The patient has the right to withdraw from the study at any time.

Financial Disclosure / Funding:

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PATIENTS AND MATERIALS

This is a Prospective, observational and analytic study, Fifty children presented by upper gastrointestinal (GIT) symptoms including recurrent abdominal pain, Hematemesis, dyspeptic epigastric pain, vomiting, attending pediatric gastroenterology endoscopy unit at Al-Hussein university hospital.

Inclusion criteria:

1. Age: from 2 to 18 years.
2. Sex: both sexes will be involved.
3. Complaint: upper gastrointestinal (GIT) symptoms including recurrent abdominal pain, Hematemesis, dyspeptic epigastric pain, vomiting.

Exclusion criteria:

1. Age less than 2 or more than 18 years.
2. Chronic use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
3. Past history of any malignant condition, chemotherapy.
4. Major gastrointestinal surgical procedures.
5. Liver cell failure, coagulopathy.
6. Chronic renal failure, urinary incontinence.
7. Congestive heart failure, endocrinal diseases (diabetes, thyroid disease).
8. Immune-compromised patients, smokers, drug or alcohol abuse.
9. Mentally disabled children and adolescents.

All patients had been subjected to the following:

History taking:

A careful history was taken from each case including, Personal history: Name, age, sex, residence, number of siblings and order between siblings. Present history: Age of onset of complaint, Nature of symptoms and duration and course of colicky attacks, perinatal history, Dietetic history and Family history.

Examination:

General examination and Local examination: Chest, heart and CNS examination and detailed abdominal examination.

Investigations:

Laboratory investigations: CBC by (sysmex XN 330), and CRP by latex agglutination test (TURBOX) plus orion Diagnostica, Finland). Liver function tests and kidney function tests by (Cobas C 111), PT, PTT, INR, and PC by (Coatron Teco M1). Stool sample for: Stool H pylori antigen by (Rapid Eco Test).

Upper GIT endoscope and biopsy: the macroscopic endoscopic features of mucosa evaluated and multiple biopsies will take from (from both diseased and healthy areas) for histopathological examination.

Ethics and patient consent: All procedures in this study had been following AL-Azhar University Ethical committee regulations, and verbal consent will be taken from all participants.

Statistical analysis: IBM SPSS-22 program (Inc, Chicago, IL, USA) has been used to preform statistical analysis. Data have been examined for normal distribution via the Shapiro Walk testing. Qualitative data have been presented as frequency and relative percentage. Chi square testing (χ^2) has been utilized to determine change among 2 or more groups of qualitative variables. Quantitative data have been presented as mean \pm SD (Standard deviation). Nondependent sample t-testing has been utilized in comparing among 2 nondependent groups of normal distribution variables (parametric data) & Mann-Whitney testing. P value < 0.05 was judged significant. ROC-curve was built to permit choice of threshold values for testing findings and comparisons of various testing approaches. Areas under ROC curves and their standard errors have been calculated via the technique of Cantor, and matched via the normal distribution, with correction for association of notes resulting from the same cases.

AUC of ROC shows: $0.90 - 1 = 0.50-0.6 = \text{fail}$. The optimal cut-off point has been recognized at point of maximum accurateness. excellent, $0.80-0.90 = \text{good}$, $0.70-0.80 = \text{fair}$; $0.60-0.70 = \text{poor}$; and

RESULTS

Our results will be demonstrated in the following tables

Table (1): Distribution of studied sample according to patient's age & sex

	Number	Percent
Age (years)		
2 – 6 years	17	34.0
6 – 12 years	18	36.0
12 – 18 years	15	30.0
Range	2-17	
Mean±S.D.	9.38±4.412	
Sex		
Male	32	64.0
Female	18	36.0

Table (1) shows demographic data of the studied group. Age ranged from 2-17 years with

mean value 9.38 ± 4.412 years. More than half of studied sample were male (64.0%).

Table (2): Distribution of studied sample according to patient's complain

Complain	Number	Percent
Recurrent abdominal pain	17	34.0
Hematemesis	11	22.0
Dyspepsia	12	24.0
Epigastric pain	20	40.0
Vomiting	20	40.0

Table (2) shows patients complain of the studied group and it shows that 17(34.0%) had Recurrent abdominal pain,

11(22.0%) had Hematemesis, 12(24.0%) had Dyspepsia, 20(40.0%) had Epigastric pain and 20(40.0%) had Vomiting.

Table (3): Distribution of studied sample according to patient's laboratory investigations

	Laboratory investigations
Hb (g/dL)	
Range	9.0-14.0
Mean±S.D.	11.90±1.384
WBCs (x10³/μL)	
Range	6-30
Mean±S.D.	11.51±5.858
Platelet (x10³/μL)	
Range	215-335
Mean±S.D.	278.46±37.148
CRP (mg/L)	
Range	4-21
Mean±S.D.	15.48±5.414
AST (U/L)	
Range	13-35
Mean±S.D.	24.84±6.560
ALT (U/L)	
Range	13-36
Mean±S.D.	25.74±7.529
PT (seconds)	
Range	11.0-13.4
Mean±S.D.	12.23±0.750
PTT (seconds)	
Range	60-70
Mean±S.D.	64.72±3.175
INR	
Range	0.80-1.10
Mean±S.D.	0.95±0.122
Packed Cell Volume (PCV) (%)	
Range	25-46
Mean±S.D.	34.96±6.484

Table (3) shows laboratory investigations of the studied group. Hb ranged from 9.0-14.0. WBCs ranged from 6-30. Platelet ranged from 215-335. CRP

ranged from 4-21. AST ranged from 13-35. ALT ranged from 13-36 .PT ranged from 11.0-13.4. INR ranged from 0.80-1.1. PCV ranged from 25-46.

Table (4): Distribution of studied sample according to patient's Stool H.pylori antigen

Stool <i>H.pylori</i> antigen	Number	Percent
Negative	8	16.0
Positive	42	84.0
Total	50	100

Table (4) shows Stool *H.pylori* antigen of the studied group and it shows that *H.pylori* antigen were detected in 42 patients (84.0%).

Table (5): Distribution of studied sample according to patient's Upper G.I.T endoscope and biopsy finding

Upper Git endoscope and biopsy finding	Number	Percent
<i>H.pylori</i>	40	80.0
Ulcer	6	12.0
Ecchymosis	2	4.0
Hyperemia	2	4.0
Total	50	100

Table (5) shows Upper G.I.T endoscope and biopsy finding of the studied group and it shows that *H.pylori* antigen were detected in 40 patients (80.0%) while 12% of the patients had ulcer, 4% had ecchymosis and 4% had hyperemia.

Table (6): Correlation between *H.pylori* stool antigen test result and Age groups & Sex

Stool <i>H.pylori</i> antigen	Positive N=42		Negative N= 8		P
	NO	%	No	%	
Age					
2-6 years	14	33	3	37	P = 0.766
6-12 years	16	38	2	25	
12-17	12	28	3	37	
Sex					
Male	29	69	3	37	P =0.884
Female	13	30	5	62	

Table (6): This table shows that there is no significant correlation between *H.pylori* stool antigen test result and Age groups & Sex.

Table (7): Correlation of Stool Ag &Endoscopic Result regarding H.pylori infection

Stool <i>H.pylori</i> antigen	Upper Git endoscope and biopsy finding			
	Negative		Positive	
	No.	%	No.	%
Negative	7	14.0	1	2.0
Positive	3	6.0	39	78.0
Kappa (agreement test)	73%			

With agreement of 73% ROC curve analysis between Upper Git endoscope and biopsy finding and Stool *H.pylori* antigen show a sensitivity of

97.50% and specificity of 70.0% with area under curve (AUC) 0.838 and highly significant p value of <0.001.

Table (8): Sensitivity& Specificity of Stool Ag test for detection of H.pylori

Sensitivity	97.50
Specificity	70.00
PPV	92.9
NPV	87.5

PPV: Positive Predicted Value

NPV: Negative Predicted Value

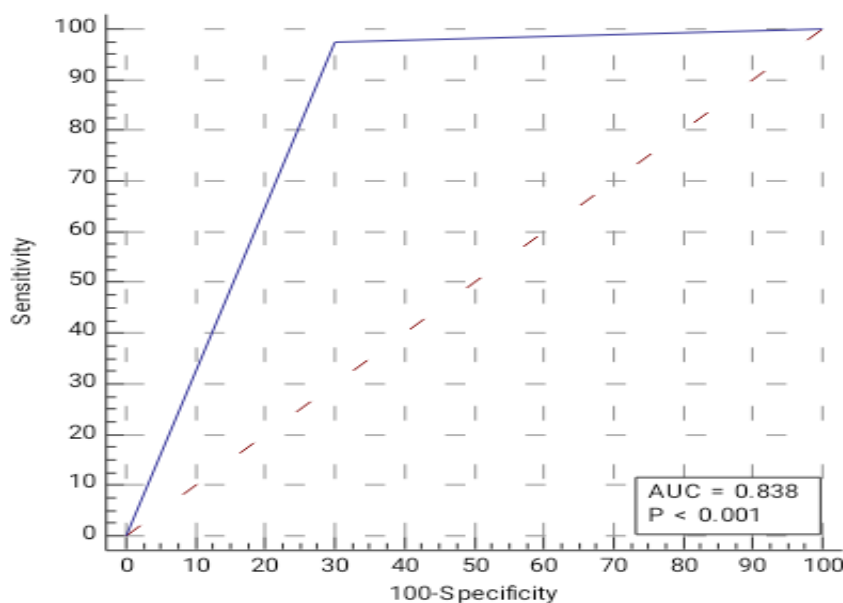


Figure (1): ROC curve analysis between Upper G.I.T endoscope and biopsy finding and Stool *H.pylori* antigen

Area Under Curve =0.838

P Value ≤ 0.001

DISCUSSION

Helicobacter pylori infection is one of the most common bacterial infections in humans, having a worldwide distribution and affecting nearly 50% of the world's population. The majority of persons infected with *H. pylori* develop chronic gastritis, but they are often asymptomatic (Reshetnyak et al., 2021).

The prevalence of *H. pylori* is inversely related to socioeconomic status, and in many developing countries it is over 80%, which is substantially higher than in industrialized countries, where it is under 40%. The prevalence of

infection with *H. pylori* among Egyptian children aged 2–17 years in Cairo is 46% (El-Shabrawi et al., 2018).

Non-invasive methods for detection of *H. pylori* infection are required to study its incidence, transmission, and clearance. They should be easy to perform and inexpensive, have a high diagnostic accuracy and be well tolerated, especially in infants and toddlers. Detection of *H. pylori* stool antigen (HPSAg) is becoming an alternative, non-invasive, simple and cost-effective diagnostic test; however, its accuracy in developing countries,

particularly in children, has not yet been well-established. To our knowledge are very limited studies compared Stool Antigen Test and upper endoscopic findings in diagnosis of H. Pylori in Egyptian Children.

Regarding demographics, we found that Age ranged from 2-17 years with mean value 9.38 ± 4.412 years. More than half of studied sample were male (64.0%).

Our study was supported by **El-Shabrawi et al., 2018** who enrolled 60 symptomatic and dyspeptic Egyptian children with a mean age of 7.2 ± 3.7 years (2–15 years) with 50% male.

Also, **Galal et al., 2019** enrolled a total of 630 Egyptian children, 325 males (51.6%) and 305 females (48.4%), were enrolled for the study. The total number of H. pylori-positive individuals was 407 (64.6%). The participants' age ranged from 1 to 15 years with a median of 7 years.

As regard patients complain of the studied group, our results showed that 17(34.0%) had Recurrent abdominal pain, 11(22.0%) had Hematemesis, 12(24.0%) had Dyspepsia, 20(40.0%) had Epigastric pain and 20(40.0%) had Vomiting.

While the study by **Galal et al., 2019** reported that the most

prevalent symptoms were Hematemesis (92%), abdominal pain (76%), Melena (44.7%), Pallor (9.6%) and Vomiting (5.9%). They also reported that Clinical symptoms and signs significantly associated with positive H. pylori infection included abdominal pain (OR = 1.823, 95% CI 1.277–2.602, P = 0.001), vomiting (P < 0.001), hematemesis (OR = 3.387, 95% CI 2.059–5.573, P < 0.001), and pallor (OR = 3.270, 95% CI 1.438–7.439, P = 0.003).

As well the study by **Abu-Zekry et al., 2013** included 150 consecutive Egyptian patients aged 5–15 years (54% male) they reported that Recurrent abdominal pain was the most frequent gastrointestinal complaint of the study population (82%), followed by anorexia (6.7%), vomiting (6.7%), and chronic diarrhea (4.7%).

As regard laboratory investigations of the studied group, our results showed that Hb ranged from 9.0-14.0 with mean value 11.90 ± 1.384 . WBCs ranged from 6-30 with mean value 11.51 ± 5.858 .

While the study by **Galal et al., 2019** reported the laboratory results for both infected and non-infected groups, they reported that the levels of serum hemoglobin

(median, interquartile range (IQR): infected = 10.6 (9.4–11.2) and non-infected = 11.0 (10.1–13.0); $P < 0.001$), ferritin (median (IQR): infected = 17.5 (9.0–60.0) and non-infected = 41.0 (15.1–60.0); $P < 0.001$), and iron (median (IQR): infected = 41.0 (25.0–71.0) and non-infected = 46.0 (34.0–70.0); $P = 0.015$) were significantly reduced in infected children. No significant association was found between infected and non-infected children as regards INR, liver enzymes, and serum albumin.

Our current study revealed by using the Stool *H.pylori* antigen of the studied group that *H.pylori* antigen was detected in 42 patients (84.0%). While using Upper GIT endoscope and biopsy finding it found that *H.pylori* antigen were detected in 40 patients (80.0%), with insignificant difference between both methods.

Choi et al., 2011 reported that the sensitivity, specificity, and accuracy of the stool test are high, with reported rates of 93.1%, 94.6%, and 93.8%, respectively.

The study by **Alzoubi et al., 2020** studied adult patients and reported that the rate of *H. pylori* detection using endoscopy was 56.7% (17/30). Heartburns (82.3%, p value = 0.019), epigastric pain (88.2%, p value =

0.007) and vomiting (70.5%, p value = 0.02) were the most significant symptoms. Family history of peptic ulcer diseases was significantly associated with an increased risk for having a *H. pylori* positive result (p value = 0.02). Compared to endoscopy, the sensitivity of 13C UBT for the diagnosis of *H. pylori* was 94.1% (16/17), while it was 76.5% (13/17) for the stool antigen test. The specificity of both tests was equal (76.9%). However, the positive predictive and negative predictive values (84.2% and 90.9%) for 13C UBT were higher than those (81.3% and 71.4%) for the stool antigen test. The accuracy of 13C UBT was 86.7% compared to 76.7% for the stool antigen test. There was an 87% agreement (20 patients out of 23) between both tests when used to assess success of the eradication therapy.

CONCLUSION

Our results revealed that the *H. pylori* was more prevalent in males with ages <10 years and the most prevalent symptoms are Recurrent abdominal pain, Hematemesis, Dyspepsia, Epigastric pain and Vomiting. Both stool antigen test and Upper G.I.T endoscope & biopsy finding give Incomparable results. There was highly significant correlation between both tests. As a non-

invasive technique the stool antigen test is more preferred than other invasive techniques as Upper G.I.T endoscope & biopsy.

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مقارنة اختبار مستضد البراز بنتائج المنظار العلوي في تشخيص الهيلكوباكتر عند الأطفال المصريين

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خلفية البحث: تعتبر جرثومة المعدة من أكثر الأمراض المعدية شيوعاً عند الأطفال والبالغين وتحدث الاصابه غالباً عند البالغين نتيجة العدوى أثناء الطفولة. نظراً لندرة الاستئصال الطبيعي للعدوى، تستمر العدوى مدى الحياة ما لم يتم تطبيق العلاج المناسب للعدوى.

الهدف من البحث: تهدف الدراسة إلى مقارنة دقة اختبار مستضد البراز المطبق على عينات البراز مع استخدام المنظار المعدي المعوي العلوي مع الخزعات في المرضى الذين يعانون من شكاوى في الجهاز الهضمي العلوي.

المرضى وطرق البحث: أجريت هذه الدراسة الاستباقية والرصدية والتحليلية على خمسين طفلاً ظهرت عليهم أعراض الجهاز الهضمي العلوي بما في ذلك آلام البطن المتكررة والقيء الدموي وآلام عسر الهضم الشرسوفية والتقيؤ في وحدة مناظير الجهاز الهضمي للأطفال بمستشفى الحسين الجامعي..

وقد خلصت الدراسة الي تراوح العمر بين 2-17 سنة. أكثر من نصف العينة المدروسة كانوا من الذكور (64.0%). فيما يتعلق بالمرضى الذين يشكون من المجموعة المدروسة، كان 17 (34.0%) يعانون من آلام بطنية

متكررة، 11 (22.0%) لديهم قيء دموي ، 12 (24.0%) يعانون من عسر الهضم، 20 (40.0%) يعانون من ألم شرسوفي و 20 (40.0%) يعانون من القيء. فيما يتعلق بمستضد جرثومة المعدة في البراز من المجموعة المدروسة، تم اكتشاف مستضد جرثومة المعدة في 42 مريضًا (84.0%). فيما يتعلق بالمنظار المعدي المعوي العلوي ونتائج الخزعة للمجموعة المدروسة، فقد تبين أن مستضد جرثومة المعدة تم اكتشافه في 40 مريضًا (80.0%). بالاتفاق على تحليل منحنى ROC بين المنظار المعدي العلوي واكتشاف الخزعة واختبار مستضد البراز وقيمة p ذات دلالة عالية.

الاستنتاج: أظهرت نتائجنا أن بكتيريا الملوية البوابية كانت أكثر انتشارًا عند الذكور الذين تقل أعمارهم عن 10 سنوات والأعراض الأكثر شيوعًا هي آلام البطن المتكررة، القيء الدموي، عسر الهضم، الألم الشرسوفي والقيء. يعطي كل من اختبار مستضد البراز ونتائج المنظار العلوي والخزعة نتائج مماثلة. كان هناك ارتباط كبير بين كلا الاختبارين. كطريقة غير جراحية، يُفضل اختبار مستضد البراز أكثر من التقنيات الغازية الأخرى مثل منظار البوابة العلوية والخزعة.